REMARKS

Claim Status

Claims 14-15, 18, and 29-31 are pending and should be examined. No new matter has been added.

Rejections under 35 U.S.C. § 103(a)

Claims 14-15, 18, and 29-31 are rejected over Moloney *et al.*, Wieles *et al.*, van Rooijen *et al*, and Murphy *et al.* Office Action, pages 2-7. Applicants respectfully traverse the grounds for this rejection.

For a proper combination of references, there must be some indicative teaching or suggestion in the prior art. MPEP § 2142. Thus, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP § 2143.01. In fact, references cannot be combined when they teach away from their combination. MPEP § 2145X.D.

Furthermore, even if there were a suggestion that implicated such a combination, the combined teachings would not have led to the claimed method. To establish a prima facie obviousness, all of the claim recitations must be taught or suggested by the prior art. MPEP § 2143.03.

With these principles as background, the PTO alleges that "Moloney *et al.* (WO 93/21320) teach a method of producing a fusion protein by introducing in a plant cell, a chimeric polynucleotide comprising a polynucleotide that regulates transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant and a heterologous protein of interest which is further linked to a polynucleotide capable of terminating transcription in a plant cell making a chimeric polynucleotide comprising a polynucleotide capable of regulating transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from a plant and a heterologous protein of interest...." Office Action, page 6. On the other hand, the PTO admits "Moloney *et al.* does not teach a method of emulsifying the *washed* oil

bodies comprising the fusion protein, wherein the heterologous protein is a thioredoxin or a thioredoxin reductase and the "portion of an oleosin" is the central domain of an oleosin wherein the fusion protein is produced in a rapeseed cell." *Id.*, page 4.

Yet, as Applicants have previously explained, Moloney *et al.* fails not only to teach "emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase" but also to disclose formulating into an emulsion a washed oil body preparation that comprises a "recombinant fusion polypeptide," as recited. For these reasons alone, Moloney *et al.* could not render the present invention obvious.

The PTO continues to rely on Wieles *et al.* in an attempt to remedy the acknowledged deficiencies of Moloney *et al.* According to the PTO, "Wieles *et al.* teaches polynucleotides encoding a thioredoxin and thioredoxin reductase." Office Action, page 4, paragraph 3. Like Moloney *et al.*, however, Wieles *et al.* fails to teach formulating a washed oil body preparation into an emulsion. For this reason, too, no permutation of Wieles and Moloney could render the presently claimed invention obvious.

Now, the PTO replaces Owen with van Rooijen, *et al.* (Biotechnology (NY). 1995 Jan; 13(1):72-7), alleging that van Rooijen *et al.* teaches a "method of production and isolation of heterologous proteins in plants cells, such as rapeseed cells, by fusing a oleosin to the heterologous protein, where the oleosin facilitates separation of the heterologous protein from other cellular proteins ... van Rooijen *et al.* also discloses that oil-bodies remain intact after aqueous extraction (or washing) ...." Office Action at page 5, paragraph 1.

To the contrary, however, van Rooijen *et al.* fails not only to teach "emulsifying the fusion protein comprising a thioredoxin or thioredoxin reductase" but also to disclose formulating into an emulsion a washed oil body preparation that comprises a "recombinant fusion polypeptide," as recited. For this reason, again, no permutation of van Rooijen, Wieles and Moloney could render the presently claimed invention obvious. Thus, the rejection is improper and should be withdrawn.

As noted, neither Moloney *et al.*, Wieles *et al.* nor van Rooijen *et al.* suggests formulating into an emulsion a *washed* oil body preparation, comprising a recombinant fusion

polypeptide that contains an oil body protein and a thioredoxin or thioredoxin reductase. Apparently in recognition of this fact, the PTO relies on Murphy *et al.*, INFORM. Vol. 4. no. 8 (August 1993), for allegedly disclosing that "oleosins act as emulsifying agents and/or as emulsion-stabilizing agents." Office Action, page 5, last paragraph.

In fact, Murphy *et al.* discloses that oleosins have a central hydrophobic domain. Still, the PTO incorrectly combines Murphy, Moloney *et al.*, Wieles *et al.*, and van Rooijen *et al.* for the context, in the prior art, of producing a fusion protein comprised of at least the central domain of an oil body protein, plus thioredoxin or thioredoxin reductase. Office Action, page 6. Invoking a motivation to have produced thioredoxin reductase inexpensively in a plant cell, where the fusion protein could be reused in catalysis, the PTO alleges that one of ordinary skill would have a reasonable expectation for (a) producing the fusion protein in a plant cell; (b) isolating the fusion protein ; and (c) formulating the fusion protein into an emulsion. *Id.*

Even if the present invention contemplated producing a "recyclable" fusion protein by formulating it into an emulsion, the PTO's own rationale still would fall short of the claimed invention. That is, the present invention provides a method for preparing an emulsion formulation by (1) obtaining intact oil bodies; (2) *washing* the intact oil bodies before preparing an emulsion; and (3) formulating the washed oil body preparation comprising substantially intact oil bodies into an emulsion. No reasonable permutation of teachings from Murphy *et al.* with those gleaned from the secondary references could have suggested an emulsion formulation. In particular, the cited combination does not disclose all of the presently recited elements and, hence, does not establish a *prima facie* case under Section 103. For at least this reason, the rejection is improper and should be withdrawn.

CONCLUSION

Applicants respectfully request that this Amendment under 37 CFR § 1.116 be entered by the Examiner, placing the claims in condition for allowance. Applicants submit that the remarks neither raise new issues nor necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either

earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the Final Action presented some new arguments as to the application of references against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention is neither anticipated nor rendered obvious in view of the references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

Respectfully submitted,

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By Reg No. 34,717

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

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